REMARKS

Claims 1-42 are present in this application and have been subjected to restriction by the Examiner under 35 U.S.C. §§121 and 372 as follows:

I. Claims 1-25 and 34, drawn to proteins and pharmaceutical compositions thereof.

II. Claims 26-33 and 35-36, drawn to nucleic acids and recombinant methods of protein production using said nucleic acids.

III. Claims 37-42, drawn to methods of inducing astroglial proliferation.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents three separate and distinct inventions. The Examiner has specifically alleged that there is no unity of inventions between Group I and Group II, as "the protein of Group I could be made by an entirely different method, rather than by the recombinant method of Group II...". The Examiner has also alleged that "the protein of Group I could be used in an entirely different method from that of Group III..." and that the "polynucleotides of Group II are not required for the method of Group III". Moreover, the Examiner contends that "the inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding technical features".

Lastly, the Examiner has alleged that "the three groups do not share the special technical features identified...".

As indicated, and in order to be fully responsive to the Examiner's requirements for restriction, applicants provisionally elect to prosecute the subject matter of Group II, Claims 26-33 and 35-36, directed to nucleic acids and recombinant methods of protein production using said nucleic acids.

Pursuant to 37 C.F.R. §§1.111 and 1.143, applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more <u>independent and distinct</u> inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. §121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent <u>and</u> distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. Group III is directed to a method of inducing astroglial proliferation in a mammal comprising administering a recombinant protein of Group I. The recombinant proteins of Group I are prepared by the methods of Group II. Moreover applicants submit that the claims of Groups I, II and III are characterized at least by the technical feature defined by SEQ ID NO:2. The Examiner alleges however that the "special technical feature of Group I is recognized in the art and therefore cannot serve as the basis for unity of invention". Applicants observe that the Examiner has not cited any art per se. Applicants submit that SEQ ID NO:2 or parts or fragments thereof are neither taught nor suggested by the prior art. As such the claims of Groups I, II and III are characterized at least by the technical feature defined by a recombinant molecule comprising SEQ ID NO:2.

Thus, according to 37 C.F.R. §1.475, the recombinant molecule comprising SEQ ID NO:2 constitutes a special technical feature which defines a contribution over the prior art and thus satisfies the requirements for unity of invention. Accordingly, Groups I-III should be examined together.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several

aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicants' financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicants' legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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